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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,643	01/14/2002	Rachel E. Meyers	MP01-016P1RCP1M	2307

7590 06/23/2004  
Jean M. Silveri  
Millennium Pharmaceuticals, Inc.  
75 Sidney Street  
Cambridge, MA 02139

EXAMINER
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SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/046,643

Applicant(s)

MEYERS ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_

### DETAILED ACTION

Claims 1-22 are pending.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

- I. Claims 1-7, 12, and 18, drawn to nucleic acid molecules, classified in class 536, subclass 23.2.
- II. Claims 8-10, drawn to polypeptides, classified in class 435, subclass 226.
- III. Claims 13 and 14, drawn to a method for detecting a polypeptide, classified in class 435, subclass 7.1.
- IV. Claims 15, in part, and 11, drawn to antibodies, classified in class 530, subclass 388.26.
- V. Claim 15, in part, drawn to a non-antibody compound that binds a polypeptide, classified in class 530, subclass 300.
- VI. Claims 16 and 17, drawn to a method for detecting a nucleic acid molecule, classified in class 435, subclass 6.
- VII. Claims 19 and 20, in part, drawn to a method for identifying a compound that binds to a polypeptide by measuring binding, classified in class 435, subclass 23.
- VIII. Claims 19 and 20, in part, drawn to a method for identifying a compound that binds to a polypeptide by measuring signal transduction, classified in class 435, subclass 23.
- IX. Claim 21, drawn to a method for modulating the activity of a polypeptide, classified in class 435, subclass 23.

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- IX. Claim 22, drawn to a method for screening for modulators of the activity of a polypeptide, classified in class 435, subclass 23.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of Invention II are related to the antibodies of Invention IV by virtue of being the cognate antigen necessary for the production of antibodies. The proteins of Invention II are also related to the binding compounds of Invention V. Although the protein and antibody, as well as the protein and binding compound, are related due to the necessary steric

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complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities and because the protein can be used in another and materially different process from the use for production of the antibody and identification of the binding compound, such as in a pharmaceutical composition in its own right.

Inventions I, IV, and V are unrelated because the products of Inventions I, IV, and V are physically and functionally distinct chemical entities.

Inventions III and VI-X are independent because the methods of Inventions III and VI-X comprise different steps, utilize different products and/or produce different results.

The methods of Invention VII-X are related to the proteins of Invention II as a product and process of using. However, Inventions VII-X are distinct from said proteins because the protein can also be used for production of an antibody and in a pharmaceutical composition in its own right.

Inventions I and VI are related as a product and process of using. The inventions are distinct because the nucleic acid molecule of Invention I can be also be used for production of the encoded protein.

Inventions IV and V are related to Inventions III, VII-X as products and process of use. The inventions are distinct because the antibodies and binding compounds of Inventions IV and V can also be used as pharmaceutical reagents or to purify the polypeptide.

Inventions III and VII-X are unrelated to Invention I because the methods of Inventions III and VII-X can neither use the nucleic acid molecules of Inventions I nor be used to make said nucleic acid molecules.

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Inventions III and VI are unrelated to the polypeptide of Invention II because the methods of Inventions III and VI can neither use the polypeptide of Invention II nor be used to make said polypeptide.

Invention VI is unrelated to the antibodies and binding components of Inventions IV and V because the methods of Invention VI can neither use the antibodies and binding components of Inventions IV and V nor be used to make said antibodies and binding components.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.



REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP 1800  
1600